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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,675	06/22/1999	RAJEEV A. JAIN	029318/0497	9275

7590

08/11/2005

FOLEY & LARDNER
3000 K STREET, SUITE 500
WASHINGTON, DC 200075109

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/337,675

Applicant(s)

JAIN ET AL.

Examiner

Susan T. Tran

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 18 July 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-22 and 25-54.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 07/18/05 have been fully considered but they are not persuasive.

Applicant argues that Desieno does not anticipate the claims because the reference neither expressly teaches the claimed rate controlling polymer, nor does it inherently do so. Contrary to the applicant's argument, Desieno does teach the claimed polymer. Desieno does not expressly call the polymer "the rate controlling polymer", however, Desieno teaches the same polymer being claimed in claim 10 (and thus, claim 1), e.g., polyvinylpyrrolidone and polyethylene glycol (see column 5, lines 1-13), namely, the rate-controlling polymer. Accordingly, Desieno anticipates the claims.

On page 15, lines 2-3, of the remarks, applicant states that "[t]he PTO and Applicant's agree here that Desieno is "silent" about the claimed rate controlling polymer and resultant controlled release nanoparticulate composition." This statement by the applicant is inaccurate. The examiner would like to state for the record that the examiner did not agree that Desieno is "silent" about the claimed rate-controlling polymer. Instead, in the 103(a) rejection over Desieno and Liversidege, in view of Friend, the examiner stated that Desieno does not teach the specific rate-controlling polymer claimed in claims 11 and 12. It is noted that claims 11 and 12 are not rejected under the 102(b) rejection by Desieno. Regarding to the resultant controlled release of the drug for a time period of from about 2 to about 24 hours, it is the position of the examiner that the resultant controlled release of the drug for a time period is inherent, because Desieno uses the claimed polymer in the over coated protective layer, e.g.,

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polyethylene glycol and polyvinylpyrrolidone. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Applicant argues that the PTO specifically relied upon passages within Desieno that not only do not support the rejection, but they also undermine the necessity element that is central to applying the doctrine of anticipation by inherency. Applicant further states that: what worse support could exist for the proposition of the overcoat polymer conferring a controlled release property than the reference itself stating precisely the contrary. In response to applicant's argument, it is not necessary for the prior art to show each and every property of the claimed product (see *In re Best*, Bolton and Shaw (CCPA) 195 USPQ 430, 10/13/1977). As discussed above, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant has not shown that the invention taught by Desieno does not have the claimed release period. The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. The burden of proof is similar to that required with respect to

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product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Applicant argues that Desieno suggests that the disclosed compositions rapidly release the nanoparticulate active agents, e.g., in 10 minutes, which is much quicker than the claimed range of about 2 to about 24 hours. See Desieno at column 17, lines 55 to column 18, lines 1-3. However, the test to determine the ease of reconstituting particles cannot conclude to be equivalent with the test to determine the release rate for the following reasons:

- 1) the drug was vortex for 10 second;
- 2) the drug was shook at 300 RPM for 10 minutes; and
- 3) the procedure did not indicate that after shaking the drug for 10 minutes, the sample is pipette immediately.

Applicant argues that Vernon discloses a drug that is suspended in a polymer matrix of at least two water-soluble and biodegradable polymers. Thus, Vernon does not suggest that the drug is poorly soluble, that it is in nanoparticulate form, and that at least one surface stabilizer is associated with the surface of the drug nanoparticulate. In response to the applicant's argument, it is noted that the limitation "water-soluble" disclosed by Vernon is referred to the polymer, not the drug. Nowhere in Vernon is the disclosure of the drug is water-soluble found. Regarding to the nanoparticulate limitation, Vernon teaches microparticulate having sizes that fall within the claimed particle size. Accordingly, Vernon does teach nanoparticle.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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